

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant	Rothenberg
Serial No	10/759,288
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Examiner	Rooney
Group Art Unit	1644
Confirmation No.	7158
Title	<b>REGULATION OF ALLERGEN INDUCED GENE</b>
Atty. Docket	CMC 163

Cincinnati OH 45202

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Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**ELECTION AND PRELIMINARY AMENDMENT**

Responsive to the September 5, 2006 Restriction in the above-referenced application,  
Applicant elects with traverse Group XXVII, encompassing claim 22.

Prior to examination of this application, please amend the application as follows:

**Amendments to the Claims** begin on page 2.

**Remarks** begin on page 6.

## AMENDMENTS TO THE CLAIMS

This version of the claims replaces all prior versions.

- 1.(WITHDRAWN) A method to mitigate an allergic response in a patient comprising enhancing expression of trefoil factor-2 (TFF2) to thereby mitigate the allergic response in the patient.
2. (WITHDRAWN) The method of claim 1 wherein the mitigation encompasses altered mucus production, promoted cell hyperplasia, and combinations thereof.
3. (WITHDRAWN) The method of claim 1 wherein expression is enhanced in an airway, lung, trachea, respiratory tract, or bronchoalveolar lavage fluid.
4. (WITHDRAWN) The method of claim 1 wherein expression is enhanced in a body part affected by an allergy.
5. (WITHDRAWN) The method of claim 4 wherein the body part is selected from the group consisting of skin, eye, nose, throat, gut, and combinations thereof.
6. (WITHDRAWN) The method of claim 1 wherein a pharmaceutical composition of a regulatory compound is administered systemically.
7. (WITHDRAWN) The method of claim 1 wherein administration is by a route selected from the group consisting of intravenously, intranasally, intratracheally, subcutaneously, intramuscularly, orally, intraperitoneally, and combinations thereof.
8. (WITHDRAWN) The method of claim 1 wherein expression is enhanced by at least one of interleukin-4 (IL-4) or interleukin-13 (IL-13).
9. (WITHDRAWN) The method of claim 1 wherein the allergic response is selected from the group consisting of allergic rhinitis, asthma, eczema, and combinations thereof.
10. (WITHDRAWN) The method of claim 8 further comprising IL-13 and signal transducer and activator of transcription (STAT) 6.

11. (WITHDRAWN) A pharmaceutical composition comprising an effector of trefoil factor-2 (TFF2) expression in a pharmaceutically acceptable formulation and amount sufficient to enhance an amount of DNA encoding TFF2, mRNA encoding TFF2, TFF2 protein, or combinations thereof.
12. (WITHDRAWN) The composition of claim 11 comprising an activator of STAT6, an activator of a Th2 cytokine, or combinations thereof.
13. (WITHDRAWN) The composition of claim 12 comprising activators selected from the group consisting of small molecule activators, oligonucleotide activators, transcriptional activators, and combinations thereof.
14. (WITHDRAWN) The composition of claim 11 in a formulation for administration to an allergic patient.
15. (WITHDRAWN) The composition of claim 11 in a formulation for administration to an asthmatic patient.
16. (WITHDRAWN) A physiological lung assessment method comprising determining a level of trefoil factor-2 (TFF2) in a patient to assess a patient condition selected from the group consisting of clinical status, phenotype, genotype, drug response, prognosis, determine single nucleotide polymorphisms, and combinations thereof.
17. (WITHDRAWN) The method of claim 16 wherein TFF2 is determined in lung fluid, lung biopsy, sputum, mucus, nasal washings, respiratory tract tissue, respiratory tract fluid, blood, and combinations thereof.
18. (WITHDRAWN) The method of claim 16 wherein TFF2 DNA, mRNA, protein, or combinations thereof are determined.
19. (WITHDRAWN) The method of claim 16 wherein an increased level of TFF2 indicates an inflammatory process.
20. (WITHDRAWN) The method of claim 16 wherein an increased level of TFF2 indicates a chronic repair process.
21. (WITHDRAWN) The method of claim 16 wherein the patient is at least one of allergic or asthmatic.

22. (CURRENTLY AMENDED) A ~~prophylactic or therapeutic~~ physiological method for a patient comprising providing trefoil factor-2 (TFF2) in a pharmaceutically acceptable composition to a lung of a patient in an amount sufficient to cause at least one of reduced lung acidity or enhanced lung epithelial cell repair, ~~thereby treating lung inflammation~~.

23. (WITHDRAWN) A treatment method comprising providing to an allergic patient an amount and formulation of a pharmaceutical composition containing at least one compound capable of differentially regulating an allergen-induced gene in a patient.

24. (WITHDRAWN) The method of claim 23 wherein the allergen-induced gene encodes trefoil factor-2.

25. (WITHDRAWN) A method to enhance repair of allergy-induced inflamed tissue comprising administering to a patient a composition comprising a regulator of trefoil factor-2 (TFF2) expression in a pharmaceutically acceptable formulation and in an amount sufficient to up-regulate TFF2 expression to result in at least one of reduced acid secretion or enhanced epithelial cell proliferation for enhanced repair of the inflamed tissue.

26. (WITHDRAWN) The method of claim 25 wherein the regulator of TFF2 expression is a Th2 cytokine.

27. (WITHDRAWN) The method of claim 25 wherein the regulator of TFF2 expression is at least one of IL-4 or IL-13.

28. (WITHDRAWN) The method of claim 25 wherein the regulator of TFF2 expression further comprises at least one of transcription factor STAT6 or transcription factor GATA6.

29. (WITHDRAWN) The method of claim 28 wherein the regulator is at least one of a small molecule activator of STAT6, a STAT6 oligonucleotide, or an activator of STAT6 transcription.

30. (WITHDRAWN) The method of claim 25 wherein the inflamed tissue is at least one of airway, lung, trachea, bronchoalveolar lavage fluid, skin, eyes, throat, or nose.

31. (WITHDRAWN) The method of claim 25 wherein the patient is allergic or asthmatic.

32. (NEW) The method of claim 22 wherein the composition is provided to a lung by a route selected from the group consisting of intravenously, intranasally, intratracheally, subcutaneously, intramuscularly, orally, intraperitoneally, and combinations thereof.

33. (NEW) The method of claim 22 wherein the composition is formulated as at least one of aerosol, drops, tablets, capsules, pills, syrups, elixirs, emulsions, or suspensions.

34. (NEW) The method of claim 22 wherein the composition is provided to at least one of airway, trachea, or bronchoalveoli.

35. (NEW) The method of claim 22 wherein the composition is provided to the lung of an allergic patient.

36. (NEW) The method of claim 22 wherein the composition is provided to the lung of an asthmatic patient.

37. (NEW) The method of claim 22 wherein at least one of lung fluid, lung biopsy, sputum, mucus, nasal washings, respiratory tract tissue, respiratory tract fluid, or blood is assessed for reduced lung acidity or enhanced lung epithelial cell repair.

## REMARKS

Claims 1-31 are pending. Claim 22 is elected and amended. New claims 32-37 are added. Claims 1-21 and 23-31 are withdrawn. The amendments and new claims are fully supported in the application as filed; no new matter is added.

Applicant traverses the Restriction requirement at least with respect to Groups XXVII and XXVIII. Both groups encompass claim 22, and the Examiner's classified both groups in the same class and same subclass. Thus, a search of this class and subclass would locate art directed to a method where TFF2 is provided to a lung in an amount sufficient to cause either reduced lung acidity or enhanced lung epithelial cell repair, so no undue burden is placed on the Examiner.

The Examiner states "... even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps" (pp. 12-13 Office Action). However, the claimed reduced lung acidity and/or enhanced lung epithelial cell repair result from a TFF2 effect on a single trigger: lung inflammation. By providing a composition comprising TFF2, both sequelae of lung inflammation may be ameliorated. Therefore, Applicant respectfully requests removal of the restriction between Groups XXVII and XXVIII.

Claim 22 is amended to generalize the method, supported at least at p. 18 lines 9-10. Efficacy of amended claim 22 may be readily assessed, e.g., by histology evidencing repair processes and by pH measurement. New claims 32-37 depend from claim 22 and recite specific formulations, administration routes, and patient status, supported at least at p. 18 lines 16-24; p. 19 line 6 and lines 14-16; and original claims 7, 14, 15, and 17.

## CONCLUSION

Applicant respectfully requests entry of the Amendment and reconsideration of the Restriction for the reasons previously analyzed.

Fees for three months' extension of time are being paid by credit card (see Electronic Fee Calculation Sheet). No other fees are believed due, but if any fees are deemed necessary, the Examiner has authorization to charge them to Deposit Account No. 23-3000.

The Examiner is invited to contact Applicant's undersigned representative with questions.

Respectfully submitted,  
WOOD, HERRON & EVANS, L.L.P.

/Beverly A. Lyman/  
Beverly A. Lyman, Ph.D.  
Reg. No. 41,961

2700 Carew Tower  
441 Vine Street  
Cincinnati OH 45202  
513 241 2324  
513 241 6234 facsimile